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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Patricia Brown et al.,

Serial No.: 10/764,818

Filed: January 26, 2004

Art Unit: 1635

Examiner: Richard Schnizer

For: **REDUCING CULLING IN HERD ANIMALS GROWTH HORMONE
RELEASING HORMONE (GHRH).**

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

CERTIFICATE OF MAILING: I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail with postage prepaid in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria 22313-1450 on February 13, 2006.

Tracy E. Giroux
(Signature)

Tracy E. Giroux
(Printed Name of Person Signing Certificate)

February 13, 2006
(Date)

RESPONSE TO RESTRICTION REQUIREMENT

In response to the Examiner's communication mailed January 11, 2006, having a deadline for response expiring Saturday, February 11, 2006, and extended until Monday, February 13, 2006, due to the deadline falling on a weekend, Applicants hereby elect to prosecute in this application the following invention, with traverse:

I. Claims 1-9, 11-20, 22-28, and 30-76, drawn to methods of decreasing involuntary cull in farm animals, improving body condition score (BCS) in farm animals, or increasing milk production in dairy cows by delivering into muscle of the animal, or into tissue of the cow, an expression construct encoding GHRH, with a further selection of a nucleic acid expression construct that encodes SeqID No.: 1.

The remaining restricted groups will be prosecuted separately under a divisional applications.

Applicants, submit that the Examiner's withdrawal of allowed Claims 58-76 in the Office Action dated August 24, 2005, in favor of a restriction requirement was highly unusual. However, Applicants believed that the Examiner's decision would have lead to issuance of the previously allowed claims contained within the elected invention. However, now that the Examiner has withdrawn his first restriction requirement of August 24, 2005 in favor of a second restriction requirement, Applicants believe both restrictions were improper. This is especially true since the Examiner has restricted 78 claims into 105 inventions. The Examiner has stated that the claims in each restricted invention (group 1-57, and 58-105) were drawn to a variety of patentably distinct nucleic acid (see page 3 of the January 11, 2006 office action), however, the original 78 claims are drawn to method claims.

Applicants hereby respectfully traverse the Examiner's decision to withdraw allowed claims and place such an unusually heavy restriction requirement the current invention. Applicants submit that the Examiner's restrictions of August 24, 2005 and further restrictions of January 11, 2006 are improper, and hereby request that the Examiner reconsider this each of the restriction requirements.

Applicants' invention includes claims drawn toward methods of decreasing involuntary cull in farm animals, improving body condition score (BCS) in farm animals, or increasing milk production in dairy cows by delivering into muscle of the animal, or into tissue of the cow, an expression construct encoding GHRH. Applicants submit these claims should **NOT** be sub-restricted into 105 distinct inventions based upon the specific polypeptide encoded in the nucleic acid expression construct. Applicants submit the Examiner's restrictions are improper because the two prerequisites for a proper restriction have not been met. The two prerequisites are as follows:

- (1) The inventions must be independent or distinct as claimed; **AND**
- (2) Examination of the inventions in a single application would create a "serious burden," (MPEP 803 and 808).

The Examiner has stated that the claims of inventions 1-57 are drawn to method of decreasing involuntary cull in farm animals, improving body conditions score (BCS) in farm animals, or increasing milk production in dairy cows by delivering into muscle of the animal, or into tissue of the cow, an expression construct encoding a growth hormone releasing hormone (“GHRH”), classified in class 514, subclass 44. However, the Examiner restricted the claims based upon compositions of patentably distinct nucleic acid.

Applicants submit the claims are drawn to **METHODS** and **NOT COMPOSITIONS**. As such, it would not be proper to restrict method claims based on each variant of a specific composition limitation, which each composition was used to carry out the same function in the method, and each composition was described as working examples in the specification. For example, if an application had method claims as follows:

“A method for hanging a picture on a wall, comprising: selecting a fastener for supporting the picture on the wall; attaching the fastener to the wall; and placing the picture on the wall attached fastener, wherein the fastener is a nail, a screw, or a bolt,”

Applicants submit that a restriction of the such method claims based upon a nail, screw or bolt would not be proper because it would be difficult for the Examiner to show two way distinctness, or that it would be a serious burden, as outlined in MPEP 806.05(a)-(c).

Similarly, Applicants’ application provides claims that are drawn to a method of producing a desired outcome in an animal by delivering a nucleic acid construct encoding a GHRH molecule. The selection of a variant construct that is supported by example in the specification can be compared to the nail, screw or bolt.

Furthermore, Applicants submit that in making a requirement for restriction in an application claiming plural species, the Examiner should group together species considered clearly unpatentable over each other, with the statement that restriction as between those species is not required. This was not done in the Office Action of January 11, 2006. Rather, groups of dozens of inventions were grouped together. For example, invention groups 1-57, and invention groups 58-105 were restricted from 78 original **METHOD** claims. Applicants submit that the Examiner’s assertion that the

distinct variants of GHRH that were claimed “*may have different functions in view of their different structures,*” was unsubstantiated, and improper. Additionally, the Examiner’s suggestion that GHRH variants have a “*acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter,*” was also unsubstantiated and improper

Support for the use of GHRH variants were directly addressed in Applicants’ specification (see paragraphs [0164]-[0167]), and Applicants have provided working examples in the specification of many different variants of GHRH having the same function as GHRH. The GHRH and functional biological equivalent of GHRH were specifically defined in paragraphs [0064] and [0065]. Furthermore, Applicants submit that the Examiner has **NOT** demonstrated a “serious burden” by showing any of the following:

- (i) separate classification of distinct inventions;
- (ii) separate status in the art and a separate field of search; or
- (iii) different field of search.

Because the Examiner has **NOT** demonstrated that the method claims can be properly restricted based upon specific expression constructs (i.e. using one way distinctness or two way distinctness), **AND** has NOT demonstrated how searching for such methods together would present a serious burden for searching, Applicants respectfully submit that restricting claims to a 105 inventions is improper according to MPEP 803, and respectfully request that invention groups 1-57 be combined into a single inventive group, and invention groups 58-105 be combined into a single inventive group. Applicants further submit that previously allowed claims are in condition for allowance.

Applicants request a telephone interview with the Examiner and the Examiner’s supervisor to discuss the highly unusual restriction requirement of the current application.

The Examiner is invited to give the undersigned a telephone call to set up this interview at the Examiner's earliest convenience.

Respectfully submitted,



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